MAR 6 2006

510(k) Summary of Safety and Effectiveness
Xia® Spinal System and Xia® 4.5 Spinal System

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Simona Voic Regulatory Affairs Project Manager Phone: 201-760-8145 FAX: 201-760-8345 Email: simona.voic@stryker.com
Date Prepared	February 3, 2006
Trade Name	Xia® Spinal System & Xia® 4.5 Spinal System
Proposed Class	Class III
Classification Name and Number	Pedicle Screw Spinal System [21 CFR 888.3070(b) (1) & (b) (2)] Spinal Interlaminal Fixation Orthosis [21 CFR 888.3050] Spinal Intervertebral Body Fixation Orthosis [21 CFR 888.3060]
Product Code	NKB, KWP, KWQ MNH, and MNI
Predicate Devices	Stryker Spine Xia® Spinal System (K053115) Stryker Spine Xia® 4.5 Spinal System (K052761) Medtronic Sofamor Danek's CD Horizon System (K032033)
Device Description	The Xia® Spinal System contains the same Stainless Steel and Titanium alloy components described in the predicate Xia® Spinal System submission cited above. The Xia® 4.5 Spinal System contains the same Titanium alloy components described in the predicate Xia® 4.5 Spinal System submission cited above. This submission adds an additional indication statement, but no new components.

Intended Use	The Xia® Spinal System and Xia® 4.5 Spinal System are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The 6mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia® Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia® Titanium Spinal System.
Summary of the Technological Characteristics	Compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was completed for the Xia® Spinal System and Xia® 4.5 Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2006

Stryker Spine
C/O Ms.Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K060361
Trade/Device Name: Xia® Spinal System & Xia® 4.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Codes: NKB, MNH, MNI, KWP, KWQ
Dated: February 8, 2006
Received: February 13, 2006

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

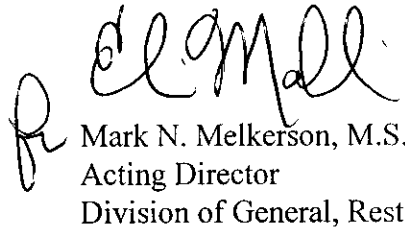
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060361

Device Name: Stryker Spine Xia® Spinal System and Xia® 4.5 Spinal System

Indications For Use:

The Xia® Spinal System and Xia® 4.5 Spinal System are intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060361